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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.				
10/645,794	08/21/2003	Andrew J. Bett	20699Y	8205				
210 MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907	7590 06/12/2007		<table border="1"><tr><td colspan="2">EXAMINER</td></tr><tr><td colspan="2">HORNING, MICHELLE S</td></tr></table>		EXAMINER		HORNING, MICHELLE S	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/645,794	Applicant(s) BETT ET AL.	
	Examiner Michelle Horning	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/6/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-83 is/are pending in the application.
- 4a) Of the above claim(s) 12-20 and 24-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to communication filed 3/6/2007. The status of the claims is as follows: claims 1-11 and 21-23 are under current examination and claims 12-20 and 24-83 are drawn to non-elected inventions and not examined here.

Claim Rejections-WITHDRAWN

35 USC 112,1st paragraph

The rejection under 35 USC 112,1st paragraph has been withdrawn due to claim amendments.

Claim Rejections-MAINTAINED

35 U.S.C. 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The following rejections made under 35 U.S.C. 103(a) are maintained:

1) Claims 1-11 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falck-Pederson, Lusky et al, Li et al, Basler and Horwitz and Mehtali et al (page 4-7 of office action); and

2) Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falck-Pederson, Lusky et al, Li et al, Mehtali et al and Magede (page 8-9 of office action).

Briefly, Falck-Pederson discloses a method of producing a replication deficient adenovirus in which the virus is deficient in both E1 and E4 functions. According to the Abstract, the adenovirus is produced in a cell that provides *in trans* the gene functions of the E1 and E4 region of an adenovirus "not belonging to the same serogroup as the replication deficient adenovirus". Mehtali et al describe using a polynucleotide encoding one or more ORF's of the E4 region, including the ORF6, which is operatively linked to the gene of interest. Applicant's arguments appeared to be entirely focused on the Falck-Pederson and Mehtali et al references and these arguments are addressed individually below (see Remarks by Applicant, pages 15-16).

Applicant's arguments have been considered but not found persuasive. Applicant points out that the Falck-Pederson reference does not teach the use of providing a heterologous E4 region *in cis* within the replication-defective adenovirus. This was also made abundantly clear by the Examiner in the most recent office action (see page 5). However, the Examiner also provided the Mehtali et al reference describing such a method in which the E4 ORFs, including ORF6, are inserted into the vector (see page 6 of the office action). Thus, this is remedied by the disclosure of Mehtali et al.

Applicant further states the following on page 15 (see Remarks):
"Furthermore, Falck-Pedersen does not speak or suggest that cell lines providing E1 and E4 of one serotype would be sufficient to complement an adenovirus of a distinct serotype which is deleted in E4. Note that the adenovirus of Falck-Pedersen are deleted in the E1 only."

In response, Falck-Pedersen may or may not suggest that "cell lines providing E1 and E4 of one serotype would be sufficient to complement an adenovirus of a distinct serotype which is deleted in E4" according the standards of the Applicant but this method is indeed taught (see entire reference of Falck-Pedersen). Further, in response to the statement "adenovirus of Falck-Pedersen are deleted in the E1 only" above and according to the invention as claimed, they do not require deletion of any additional or special regions of the adenovirus in addition to its E1. Thus, the E4 region of the adenovirus may remain intact; however, the vector requires an E4 region that is of the same serotype as the E1 from the complementing cell.

Applicant describes how the teachings of Falck-Pedersen do not match specific embodiments in paragraph 4, page 15 (see Remarks). The Examiner would like to point out that it is the claims with its limitations that are under consideration, not specific embodiments within the specification.

In addressing the arguments regarding the teachings of Mehtali et al made by Applicant, Examiner would like to point out the following recitation made in the previous office action on page 6:

"it is also possible that the vector is constructed by deleting all E4 sequences, in particular all E4 ORFs, and inserting certain E4 ORFs from the same or other adnoviurs backbones in the adenoviral vector at a location where the E4 region normally resides or at a different location, e.g. in place of the deleted E1 or E3 region". This is found in paragraph 16 of Mehtali et al.

While the Applicant asserts there is no motivation to combine the teachings of Falck-Pedersen and Mehtali et al, the Examiner addressed the harmful effects the gene function of the E4 region has on the host cell (page 5 of the office action). Further, the Examiner provided a particular discussion regarding the functional interaction between serotypes is "absolutely conserved", and the essential gene products of the E1 and E4 regions should be derived from the same serotype (page 5 of the office action, taught by Falck-Pedersen in column 8). Given this teaching and that Mehtali et al disclose E4 regions that are *in cis*, the limitations have been met and the arguments are not found persuasive.

Lastly, Applicants assert that Megede et al does not contribute to the art in terms of methods related to adenovirus. While the Examiner agrees, the reference teaches that HIV-1 gag is an important target for the host cell-mediated immune control of the virus during natural infection; thus, this reference provides ample motivation for using gag in a replication-defective adenovirus for propagation.

Conclusions

No argument is found persuasive and no claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Michelle Horning
Patent Examiner



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